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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,254	02/13/2001	Motasim Sirhan	020460000930	1701

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,254	SIRHAN ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-44,46-51,60 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-44, 46-51, 60, and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 20, 2006 have been fully considered but they are not persuasive. The applicant has again argued that each of the applied references do not disclose the claimed rate or a delayed release. The examiner disagrees. Again, the amount of drug disclosed by Gregory is the amount of mycophenolic acid alone, not the amount of mizoribine (which is used with the mycophenolic acid in combination), therefore this argument that Gregory's amount of mizorbine is 10,000 fold the applicants amount, is moot. Also, the milligrams disclosed, is per kilogram of implant carrier, therefore, the actual drug amount present would be less than a millimeter, since a stent weighs no where near a kilogram. Further, the general conditions of the claim are present, a stent with mizoribine impregnated, for the same purpose as the applicant, to inhibit restenosis, therefore the rate at which it releases is not inventive since it would be obvious to optimize the already present conditions (see below).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-44, 48-49, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 5,283,257, cited previously). Referring to claims 60 and 39-41, Gregory discloses a method of inhibiting restenosis in a vessel comprising implanting a vascular prosthesis comprising a scaffold (stent impregnated with drugs; col.3, lines 48-53; col.8, lines

30-35) having means (impregnation means; thus may be portions of the stent that "impregnate" the drug) thereon for releasing mizoribine in the vessel, and releasing mizoribine (mizoribine is disclosed to be used in combination with other drugs; col.4, lines 17-31; col.6, lines 45-52, 59-63) from the prosthesis to inhibit smooth muscle cell proliferation, wherein substantial release of the mizoribine is delayed following implantation (inherently, there is some delay following implantation, since the drugs are disclosed to be "impregnated" within the stent, therefore, there will be some delay for the drug to reach or exit the surface of the stent; amount of delay dependent on the rate, see below). Although Gregory discloses testing different amounts of drugs until the optimum effect of the drug is reached (col.9, lines 6-15), Gregory does not expressly disclosed the exact rate claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed release rates, since wherein the general conditions of a claim are disclosed in the prior art (stent with impregnated mizoribine in an optimal amount for the desired implantation technique) it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 42-44, Gregory discloses mizoribine combined with mycophenolic acid (col.4, lines 17-31; col.6, lines 45-52, 59-63).

Referring to claims 48-49, Gregory discloses the drugs to be impregnated into the stent, therefore, portions of the stent act as a diffusion barrier for the drug.

Claims 39-44, 46-51, 60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US 6,071,305, cited previously) in view of Gregory et al. (US

5,283,257, cited previously). Referring to claims 60 and 42-44, Brown discloses a method of inhibiting restenosis in a vessel (col.4, lines 61-67) comprising implanting a vascular prosthesis comprising a scaffold (stent 11) having means thereon *for* releasing mizoribine in the vessel (release means may be considered openings 22, biodegradable matrix 27, or porous membrane 34), and releasing a drug (23) from the prosthesis that inhibits smooth muscle cell proliferation (col.5, lines 6-17), wherein substantial release of the drug (23) is delayed following implantation (inherently, there is some delay following implantation, since Brown has disclosed the *same release means* as the applicant, such as biodegradable matrices, diffusion membranes, etc. therefore, Brown's drug inherently will react in the same manner as the applicant, since they both control the rate of release; basically, the drug will be delayed to get to the surface or exit the stent, because it takes time to travel through the diffusion barrier or for the degradable matrix to degrade or dissolve and inherently there will be a delay of release from the stent). Brown discloses use of drugs that inhibit restenosis and smooth muscle growth (col.4, lines 61-67; col.5, lines 6-17), however does not expressly discloses any of the specific drugs of this category, such as mizoribine or mycophenolic acid as claimed. Gregory teaches in the same field of drug delivery stents, that both mizoribine and mycophenolic acid are in the category of restenosis and smooth muscle cell growth prevention drugs (col.3, lines 60-64; col.4, lines 17-31; col.6, lines 45-52, 59-63), and additionally, which may be used with stents (col.3, lines 48-52; col.8, lines 31-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown's stent having restenosis and smooth muscle cell growth prevention drugs, with Gregory's teaching that mizoribine and mycophenolic acid are specific

restenosis and smooth muscle cell growth inhibition drugs useful on vascular stents, to provide the stent with a particular drug of choice.

Further referring to claim 60 and 39-41, although Brown in view of Gregory discloses control of the rates by various means, in order to optimize the rate of release, Brown in view of Gregory does not expressly disclosed the exact rate claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed release rates, since wherein the general conditions of a claim are disclosed in the prior art (stent with impregnated mizoribine in an optimal amount for the desired implantation technique) it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 46-49, Brown discloses releasing drugs from a reservoir (20) or somewhere on the prosthesis by a degradable material/matrix (27; col.8, lines 61-67) or non-degradable matrix/barrier (pores in stent, col.7, lines 22-24; membrane 34, col.9, lines 10-17).

Referring to claims 50-51, Brown discloses applying the drug and matrix by the methods claimed (col.12, lines 37-47).

Claims 39-44, 46-51, 60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. (US 6,774,278, cited previously) in view of Gregory et al. (US 5,283,257, cited previously). Referring to claims 60 and 42-44, Ragheb discloses a method of inhibiting restenosis in a vessel (col.5, lines 38-42) comprising implanting a vascular prosthesis comprising a scaffold (stent 12) having means thereon for releasing mizoribine in the vessel (release means may be considered porous coatings 20, 24), and releasing a drug (18, 22) from the

prosthesis that inhibits smooth muscle cell proliferation (col.5, lines38-42), wherein substantial release of the drug (18, 22) is delayed following implantation (inherently, there is some delay following implantation, since Ragheb has disclosed the *same release means* as the applicant, such as biodegradable and diffusion coatings, etc. therefore, Ragheb's drug inherently will react in the same manner as the applicant, since they both control the rate of release; basically, the drug will be delayed to get to the surface or exit the stent, because it takes time to travel through the diffusion barrier or for the degradable coating to degrade or dissolve and inherently there will be a delay of release from the stent). Ragheb discloses use of drugs that inhibit restenosis and smooth muscle growth, particularly, the class of immunosuppressive agents (col.4, line 4), however does not expressly discloses any of the specific drugs of this category, such as mizoribine or mycophenolic acid as claimed. Gregory teaches in the same field of drug delivery stents, that both mizoribine and mycophenolic acid are in the category of restenosis and smooth muscle cell growth prevention drugs (col.3, lines 60-64; col.4, lines 17-31; col.6, lines 45-52, 59-63), and additionally, which may be used with stents (col.3, lines 48-52; col.8, lines 31-34). Further, they are specific immunosuppressive agents (as admitted in applicants specification). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Ragheb's stent having restenosis and smooth muscle cell growth prevention drugs such as immunosuppressive agents, with Gregory's teaching that mizoribine and mycophenolic acid are specific restenosis and smooth muscle cell growth inhibition drugs (particularly immunosuppressive agents) useful on vascular stents, to provide the stent with a particular drug of choice.

Further referring to claim 60 and 39-41, although Ragheb in view of Gregory discloses control of the rates by various means (amount of drug, size of reservoir, porous coatings), in order to optimize the rate of release, Ragheb in view of Gregory does not expressly disclosed the exact rate claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the claimed release rates, since wherein the general conditions of a claim are disclosed in the prior art (stent with impregnated mizoribine in an optimal amount for the desired implantation technique) it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 46-49, Ragheb discloses releasing drugs from a reservoir (see fig.5, 10A-10D) or somewhere on the prosthesis (as a layer) by a degradable material/matrix (col.3, lines 34-36) or non-degradable matrix/barrier (porous layer; col.3, lines 24-29; col.20, lines 22-31).

Referring to claims 50-51, Ragheb discloses applying the drug and matrix by the methods claimed (col.3, lines 53-60; col.4, lines 60-62; col.11, lines 64-67).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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